

Application No. 10/692,117  
Amendment "A" dated March 22, 2005  
Reply to Office Action mailed November 16, 2004

### REMARKS

Applicant extends appreciation to the Examiner for the interview granted to applicant's representative. Claims 1 – 60 remain pending, and have been amended as proposed at the interview. Specifically, independent claims 1, 39 and 58 have been amended, and thus are presented for reconsideration with their corresponding dependent claims (2 – 38, 40 – 55 and 58 – 60, respectively). Independent claim 56 and dependent claim 57 were allowed and accordingly are not amended.

As presented herein for reconsideration, independent claim 1 is directed to a shaped dental bleaching composition having a tray-like configuration. The dental bleaching composition is comprised of an adhesive layer that comprises a substantially solid adhesive composition that has increased adhesiveness to teeth when moistened by saliva or water. The adhesive composition also comprises at least one tooth adhesion agent that at least partially contributes to increased adhesiveness to teeth, and the adhesive layer has sufficient rigidity to substantially maintain the adhesive layer in the tray-like configuration so that it is adapted for handling and placement onto the teeth. Lastly, the dental bleaching composition also includes a dental bleaching gel, adjacent to an inner surface of the adhesive layer, and the gel comprises at least one dental bleaching agent, at least one tackifying agent, and a liquid or gel carrier.

Independent claim 39 defines an article of manufacture in terms essentially the same as claim 1, except that claim 39 also includes a barrier layer of moisture-resistant material in the shape of dental tray. Independent claim 58 is directed to a method of manufacturing a shaped dental bleaching composition. The method includes mixing together a tooth adhesion agent and a solvent to form an adhesive composition intermediate, then removing at least a portion of the solvent so as to form an adhesive layer that is substantially solid and has sufficient rigidity to substantially maintain a tray-like configuration so as to be adapted for handling and application to a patient's teeth. The tooth adhesion agent at least partially contributes to increased adhesiveness to teeth when moistened with saliva or water. Lastly, the method includes placing a dental bleaching gel adjacent to an inner surface of the tray-like configuration formed by the adhesive layer.

In the Office Action all the claims were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent Application Publication 2002/0081555 A1 (Wiesel) as modified by teachings

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from U.S. Patent Application Publication 2003/0194382 A1 (Chang et al.).<sup>1</sup> Even if the asserted combination of teachings from the references were proper,<sup>2</sup> it still does not render the claimed invention as presented herein for reconsideration obvious. As noted at the interview, nothing in the references of record, either singly or in combination, anticipates or makes obvious a dental

<sup>1</sup> Chang et al. qualifies as a "prior art" reference, if at all, under 35 U.S.C. § 102(a). Applicant reserves the right to challenge the status of Chang et al. as a proper reference should such become necessary or desirable. Accordingly, any statement herein in reference to Chang et al. is simply made assuming for purposes of argument that Chang et al. is a proper qualifying reference.

<sup>2</sup> As noted at the interview, the asserted combination of teachings from Wiesel and Chang et al. do not provide a *prima facie* case that is sufficient to sustain the asserted rejection of independent claims 1, 35 and 55 as obvious over the teachings of those two references. In particular, Wiesel, the primary reference relied upon, discloses a delivery system for a person's teeth that includes a gel having a therapeutic agent, and in which (see, e.g., figures 1 – 3, and paragraph 0022) the gel [16] is supported and carried in a channel [14] formed in the central area of a strip of core material [12]. The core material [12] also functions as a gum protective liner. The core [12] and gum protective liner is made of a biodegradable material or of a similar material that can be washed or brushed away. Preferably the core material [12] is "a 0.5% cellulose and 0.1% carbopol solution that is freeze dried" to form a material that "is a solid sheet and is flexible and adherent to the teeth and gum-line . . . but is also somewhat viscous and tacky." (Wiesel at ¶¶ 0030-0031). A release liner [18] is applied to the top of the combined gel [16] and core [12] and is removed to expose the gel when the system is to be applied to the teeth. A releasable backing layer [20] covers the lower surface of the core and supports the gel [16] and core [12] and functions as an applicator for the system. In use, the release liner [18] is removed and the core [12] is fitted to the teeth with the gel [16] also in contact with the teeth, with the core material [12] providing a protective covering for the gums as mentioned. Once the core [12] has been fitted and molded to the teeth, the backing layer [20] is removed, leaving just the core material [12] and the gel [16] worn on the teeth. This accomplishes a major objective of Wiesel's invention, which, as noted at ¶ 0020, is "to provide a delivery system for whitening a person's teeth which remains on the teeth *without the aid of a carrier or other type of support means so as to be less obvious to others.*" (Emphasis added). Thus, as also noted by Wiesel (¶ 0022), "After a desired period of time, the core with the agent is washed off, brushed off, pulled off, or is allowed to simply dissolve."

The Examiner's Action acknowledges (p. 2) that "the adhesive disclosed by Wiesel does not have increased adhesiveness to teeth when moistened." However, the Examiner's Action then asserts (p. 2) that "It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the adhesive of Wiesel with that taught by Chang, because the adhesive of Chang is easier to handle." However, this overlooks the clear contrary nature and teaching of Chang et al. relative to providing "a dry type patch [which,] according to the present invention . . . is characterized in that the active material does not stick to the user's skin . . . because the active material reservoir layer containing peroxide is protected by one or more layers." (Chang et al. at ¶ 0020). In other words, Chang et al. provides "a multi-layer structure of three or more layers comprising a contact adhesive layer which is substantially devoid of teeth whitening agent and consists essentially of a hydrophilic glass polymer, an active material reservoir layer which contains a peroxide as a teeth whitening agent and a backing layer." (Chang et al. at ¶ 0019).

It is clearly inconsistent to replace Wiesel's sticky, viscous core material, which also serves as a barrier to the teeth, and which requires an applicator in the form of the backing liner, with Chang et al.'s dry adhesive which is placed over the active bleaching layer, not adjacent it. Chang et al.'s adhesive does not and cannot serve as a protection to the gums, a primary object of Wiesel's core. Moreover, contrary to Wiesel, Chang et al.'s dry patch requires the liner to remain on the teeth, again something expressly taught as disadvantageous in Wiesel. Thus, Chang et al.'s dry patch is clearly inconsistent with the bleaching system of Wiesel for at least the reasons noted, making the asserted combination inappropriate. In general, a reference "teaches away" if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant, clearly the case here in view of the inconsistency in the two very different kinds of bleaching systems disclosed in Wiesel and Chang et al.

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bleaching composition that has an adhesive layer having sufficient rigidity to substantially maintain the adhesive layer in a tray-like configuration so that it is adapted for handling and placement onto the teeth, particularly when used in combination with a dental bleaching gel that comprises at least one active agent, at least one tackifying agent, and a liquid or gel carrier. Indeed, as reflected in the interview summary record, an adhesive layer that "has sufficient rigidity to maintain the tray-like configuration . . . is not found in the art of record and appears to advance the claims over the art subject to review of the final amendment and the update of the search."<sup>3</sup> Accordingly, for the reasons noted, favorable reconsideration and allowance is respectfully requested.

In the event the Examiner finds any remaining impediment to allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 24 day of March, 2005.

Respectfully submitted,



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<sup>3</sup> Applicant also notes for the record that commonly owned co-pending application SN10/444,242 was also brought to the Examiner's attention during the interview, so that art from that case could also be cross checked by the Examiner, if desired, when updating the search of the art.